

## CLAIMS

We claim:

1. A method of determining heparin-induced thrombocytopenia II complex (HiT II)

comprising:

5 testing a first blood sample to determine a first blood sample characteristic in the presence of heparin;

testing a second blood sample to determine a second blood sample characteristic in the absence of substantial platelet activation; and

10 comparing the first blood sample characteristic to the second blood sample characteristic to determine the presence of HiT II.

2. The method of claim 1, wherein the first blood sample characteristic comprises at least one of a clot strength measurement, a clot elasticity measurement, a clot rate of formation measurement, a clot time to formation measurement, a clot rate of lysis

15 measurement of the first blood sample and the second blood sample characteristics comprises at least one of a clot strength measurement, a clot elasticity measurement, a clot rate of formation measurement, a clot time to formation measurement, a clot rate of lysis measurement of the second blood sample.

20 3. The method of claim 1, wherein the second blood sample characteristic represents a fibrin contribution to hemostasis.

4. The method of claim 1, wherein the step of testing a second blood sample comprises testing a second blood sample prepared to activate fibrin formation.

5. The method of claim 1, wherein the step of testing a second blood sample comprises testing a blood sample prepared to substantially completely suppress platelet activation.

6. The method of claim 1, wherein the step of testing a second blood sample comprises testing a blood sample prepared with a quantity of heparin sufficient to substantially completely suppress platelet activation.

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7. The method of claim 1, wherein the first blood sample characteristic represents a contribution to hemostasis of activated platelets in the presence of HiT II.

8. The method of claim 1, wherein the step of testing a first blood sample comprises testing a first heparinized blood sample prepared with a first quantity of heparin and a second heparinized blood sample prepared with a second quantity of heparin, different than the first quantity of heparin.

9. The method of claim 1, wherein each of the first blood sample and the second blood sample comprises a platelet rich plasma (PRP)-patient plasma mixture.

10. The method of claim 1, wherein each of the first blood sample and the second blood sample comprises patient whole blood.

11. The method of claim 1, wherein each of the first blood sample and the second blood sample comprises an activator.

5 12. An apparatus for determining heparin-induced thrombocytopenia II complex (HiT II) comprising:

means for testing a first blood sample to determine a first blood sample characteristic in the presence of heparin;

10 means for testing a second blood sample to determine a second blood sample characteristic in the absence of substantial platelet activation; and

means for comparing the first blood sample characteristic to the second blood sample characteristic to determine the presence of HiT II.

13. The apparatus of claim 12, wherein the first blood sample characteristic comprises at  
15 least one of a clot strength measurement, a clot elasticity measurement, a clot rate of formation measurement, a clot time to formation measurement, a clot rate of lysis measurement of the first blood sample and the second blood sample characteristics comprises at least one of a clot strength measurement, a clot elasticity measurement, a clot rate of formation measurement, a clot time to formation measurement, a clot rate of lysis  
20 measurement of the second blood sample.

14. The apparatus of claim 12, wherein the second blood sample characteristic represents a fibrin contribution to hemostasis.

15. The apparatus of claim 12, wherein the second blood sample comprises a blood sample prepared without heparin.

5 16. The apparatus of claim 12, wherein the second blood sample comprises a blood sample prepared to substantially completely suppress platelet activation.

17. The apparatus of claim 12, wherein the second blood sample comprises a blood sample prepared with a quantity of heparin sufficient to substantially completely suppress  
10 platelet activation.

18. The apparatus of claim 12, wherein the first blood sample characteristic represents a contribution to hemostasis of activated platelets in the presence of HiT II.

15 19 The apparatus of claim 12, wherein the first blood sample comprises a first heparinized blood sample prepared with a first quantity of heparin and a second heparinized blood sample prepared with a second quantity of heparin, different than the first quantity of heparin.

20 20. The apparatus of claim 12, wherein each of the first blood sample and the second blood sample comprises a platelet rich plasma (PRP)-patient plasma mixture.

21. The apparatus of claim 12, wherein each of the first blood sample and the second blood sample comprises patient whole blood.

22. The apparatus of claim 12, wherein each of the first blood sample and the second  
5 blood sample comprises an activator.

23. A kit for use with a blood hemostasis analyzer for determining heparin-induced thrombocytopenia II complex (HiT II), the kit comprising:

a plurality of testing vessels, each testing vessel configured to hold a blood sample for  
10 testing in the blood hemostasis analyzer;

a quantity of heparin sufficient to prepare at least one heparinized blood sample for testing; and

a quantity of activator sufficient to activate at least the heparinized blood sample and a non-heparinized blood sample.

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24. The kit of claim 23, further comprising a quantity of PPACK sufficient to prepare at least two blood samples for testing.

25. The kit of claim 23, the quantity of heparin being sufficient to prepare at least one  
20 heparinized blood sample for testing and a second sample, wherein the second sample is prepared with a quantity of heparin sufficient to substantially completely suppress platelet activation.

26. The kit of claim 23, the quantity of heparin being separated into a plurality of vials corresponding to each of a plurality of blood sample to be prepared for testing.

27. The kit of claim 23, wherein the quantity of heparin and the quantity of activator are

5 separately packaged.